

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION

)
) MDL No. 1456
)

) Civil Action No. 01-CV-12257 PBS
)

THIS DOCUMENT RELATES TO
01-CV-12257-PBS AND 01-CV-339

) Judge Patti B. Saris
) Chief Magistrate Judge Marianne B. Bowler
)

**LOCAL RULE 56.1 COUNTER-STATEMENT OF
DEFENDANTS BRISTOL-MYERS SQUIBB COMPANY, ONCOLOGY
THERAPEUTICS NETWORK CORPORATION AND APOTHECON, INC. IN
OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT
AGAINST ALL TRACK 1 DEFENDANTS**

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Apothecon, Inc.*

Pursuant to Local Rule 56.1, defendants Bristol-Myers Squibb Company, Oncology Therapeutics Network Corp. and Apothecon, Inc. (collectively, “BMS”) submit this counter-statement to “Plaintiffs’ L.R. 56.1 Statement of Undisputed Material Facts In Support of Motion for Partial Summary Judgment Against All Track 1 Defendants” (“Plaintiffs’ Statement”). BMS responds below only to those paragraphs in Plaintiffs’ Statement that concern all Track 1 Defendants jointly or BMS specifically. All allegations not admitted in BMS’ responses below are hereby disputed. Paragraph numbers correspond to those in Plaintiffs’ Statement.

¶	<u>Plaintiffs’ Statement</u>	<u>BMS’ Response</u>
1.	AWP was the reimbursement benchmark for Part B Drugs under Medicare during the class period.	Admitted that AWP has been used in various Medicare Part B reimbursement formulae during the class period. Its first use in a Medicare reimbursement-related context was in 42 C.F.R. § 405.517 (1992), where it was used by the Health Care Financing Administration to describe one of two alternative bases for reimbursement for medicines covered under Medicare Part B, namely “the lower of the estimated acquisition cost or the national average wholesale price of the drug.” The term was subsequently used by Congress in the Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o), as part of a formula that provided for reimbursement based on the lesser of the amount charged by the provider or 95% of AWP. The term was then used by Congress in the Medicare Modernization Act, 42 U.S.C. § 1395W-3a(c), as part of a formula that provided for reimbursement based on 85% of AWP.
2.	Each Track 1 Defendant knew that AWP was the reimbursement mechanism for Part B drugs during the class period.	Admitted that BMS was aware of the use of AWP as described above in response to Paragraph 1 of Plaintiffs’ Statement.

¶	<u>Plaintiffs' Statement</u>	<u>BMS' Response</u>
3.	Each Track 1 Defendant caused AWP's to be published for each of their subject drugs.	Disputed as to BMS. BMS provided Wholesale List Prices ("WLPs") to trade industry publications for the subject drugs. Kaszuba Aff. ¶¶ 1-2; Szabo Decl. ¶ 5. ¹ BMS had no control over whether or how the publications produced their AWP's. Kaszuba Aff. ¶ 2; Deposition of Patricia K. Morgan ("Morgan Dep.") Tr. 230, annexed to the Edwards Decl. as Ex. D; <u>see also</u> Edwards Decl. Ex. E; ² Tretter Decl. ¶¶ 3-5, Exs. 2-4. ³
8.	BMS caused AWP's for all of its drugs to be published.	Disputed as to BMS. BMS provided WLP's to trade industry publications for the subject drugs. Kaszuba Aff. ¶¶ 1-2; Szabo Decl. ¶ 5. BMS had no control over whether or how the publications produced their AWP's. Kaszuba Aff. ¶ 2-4; Morgan Dep. Tr. 230, annexed to Edwards Decl. as Ex. D; <u>see also</u> Edwards Decl. Ex. E; Tretter Decl. ¶¶ 3-5, Exs. 2-4.
9.	BMS controlled the AWP's for its subject drugs by reporting wholesale list prices with full knowledge of the mark-up factors that the publishers would use to create the AWP's.	Admitted that BMS reported WLP's. Kaszuba Aff. ¶¶ 1-2; Szabo Decl. ¶ 5. BMS disputes being able to control the AWP's for its subject drugs or having "full knowledge" of what mark-up factor the publications might use. Morgan Dep. Tr. 230, annexed to Edwards Decl. as Ex. D; <u>see also</u> Edwards Decl. Ex. E; Tretter Decl. ¶¶ 3-5, Exs. 2-4.
10.	BMS internally published the AWP's for its products.	BMS admits that it included AWP's, among other prices, such as WLP, FSS, AMP, BP, in price lists that certain BMS sales and marketing personnel received. Deposition of Denise Kaszuba ("Kaszuba Dep.") Tr. 46-51; 109-111, annexed to Berman Decl. as BMS Ex. 3. ⁴

¹ The "Kaszuba Aff." refers to the Affidavit of Denise M. Kaszuba submitted in support of BMS's Motion For Summary Judgment. The "Szabo Decl." refers to the Declaration of Zoltan Szabo submitted in support of BMS's Motion For Summary Judgment.

² The "Edwards Decl." refers to the Declaration of Steven M. Edwards, dated March 15, 2006, in support of BMS's Motion For Summary Judgment.

³ The "Tretter Decl." refers to the Declaration of Lyndon M. Tretter, dated April 6, 2006, in opposition to Plaintiffs' Motion for Partial Summary Judgment.

⁴ The "Berman Decl." refers to the Declaration of Steven W. Berman, dated March 15, 2006, in support of Plaintiffs' Motion for Partial Summary Judgment.

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11.	BMS's wholly-owned specialty distributor OTN republished AWP's for BMS subject drugs.	Admitted that OTN was a wholly-owned subsidiary of BMS's from 1996 to 2005 and that OTN was a specialty distributor of oncology products. In or around 2000, OTN offered a computerized service in which a customer could search for a (then) current AWP on a drug product from <u>any</u> manufacturer (not just BMS) that the customer had purchased from OTN. Deposition of Marsha Peterson ("Peterson Dep.") Tr. 114-115, 146-153, annexed to Tretter Decl. as Ex. 9; <u>see also</u> Deposition of John F. Akscin ("Akscin Dep.") Tr. 111-112, annexed to Berman Decl. as BMS Ex. 4.
12.	OTN published online reports to which customers subscribed, including the "AWP Report," which contained a list of current AWP's.	BMS admits that, in or around 2000, OTN permitted a customer to search a computer database for a (then) current AWP on a drug product from <u>any</u> manufacturer (not just BMS) that the customer had purchased from OTN and that the program permitted the customer to place the result of that search in report form. Peterson Dep. Tr. 114-115, 146-153, annexed to Tretter Decl. as Ex. 9; Peterson Dep. Ex. 6 at BMS/AWP 001486072-6074, annexed to Berman Decl. at BMS Ex. 64; <u>see also</u> Akscin Dep. Tr. 111-112, annexed to Berman Decl. at BMS Ex. 4.
13.	OTN published the "AWP/Price Report," which contained the AWP's for drugs that OTN clients had purchased, and the billing unit for each particular drug.	BMS admits that, in or around 2000, OTN permitted a customer to search a computer database for a (then) current AWP on a drug product from <u>any</u> manufacturer (not just BMS) that the customer had purchased from OTN and that the program permitted the customer to place the result of that search in report form. One iteration of the report also indicated the amount of a drug that constituted a billing unit under Medicare Part B regulations. Peterson Dep. Tr. 114-115, 147-152, annexed to Tretter Decl. as Ex. 9; Peterson Dep. Ex. 6 at BMS/AWP 001486072-6074, annexed to Berman Decl. at

¶	<u>Plaintiffs' Statement</u>	<u>BMS' Response</u>
		BMS Ex. 64.
39.	The AWP's that each Track 1 Defendant caused to be published neither reflected an average nor included the discounts called for by OIG Guidelines.	Disputed as to BMS. BMS provided WLPs to trade industry publications for the subject drugs. Kaszuba Aff. ¶ 1. BMS had no control over whether or how the publications produced their AWP's. Kaszuba Aff. ¶ 2; Morgan Dep. Tr. 230, annexed to Edwards Decl. as Ex. D; Tretter Decl. ¶¶ 3-5, Exs. 2-4. BMS further states that the "OIG Guidelines" do not call for either WLP or AWP to reflect average prices or include discounts.
40.	Each Track 1 Defendant manipulated and marketed spreads.	Disputed as to BMS. See response to Paragraph 46.
45.	BMS's AWP's neither reflected an average nor met OIG Guidelines.	Disputed. BMS provided WLPs to trade industry publications for the subject drugs. Kaszuba ¶ 1. BMS had no control over whether or how the publications produced their AWP's. Kaszuba Aff. ¶ 2; Morgan Dep. Tr. 230, annexed to Edwards Decl. as Ex. D; Tretter Decl. ¶¶ 3-5, Exs. 2-4. BMS further states that the "OIG Guidelines" do not call for either WLP or AWP to reflect average prices or include discounts.
46.	BMS purposefully manipulated and marketed spreads.	Disputed. BMS did not increase WLP on the subject drugs unless it believed it could obtain sales at that increase price. Szabo Decl. ¶ 3. Further, once a subject drug became subject to generic competition, BMS generally no longer increased WLP. Szabo Decl. ¶ 3; <u>see also</u> Deposition of Christof A. Marre ("Marre Dep.") Tr. 86, annexed to Berman Decl. at BMS Ex. 2. After generic entry, BMS had to discount to those customers who would otherwise switch to the generic, but the discounting was for the purpose of responding to competitive marketplace forces, not to "manipulate spread." Szabo Decl. ¶ 4; Marre Dep. Tr. 85-98, annexed to Berman Decl. at BMS Ex. 2. Moreover, BMS continued to make sales to other customers at

¶	<u>Plaintiffs' Statement</u>	<u>BMS' Response</u>
		or close to WLP. Bell BMS Decl. ¶ 21, Exs. D & E. ⁵ Finally, BMS did not “market spread;” rather, when asked it would provide truthful information about the AWP of a BMS drugs and its cost relative to a competing drug. <u>See</u> Edwards Decl. ¶ 8, Ex. G (excerpts of deposition transcripts of BMS sales representatives).
47.	BMS knew that its subject drugs were sold at prices well below AWP.	Admitted that BMS knew that at all relevant times that at least some proportion of its subject drugs were sold at or around WLP, which had historically been 16.6 to 20% below industry publications' AWP. <u>See</u> Kaszuba Dep. Tr. 100, annexed to Berman Decl. as BMS Ex. 3. Also admitted that BMS offered discounts below WLP.
48.	BMS created spreads through confidential contract pricing, rebates and other forms of discounting.	Admitted that BMS engaged in confidential contract pricing, rebates and other forms of discounting. Disputed that these practices were for the purpose of “creat[ing] spread” as opposed to responding to competitive marketplace forces. <u>See</u> Marre Dep. Tr. at 40-41, 79, annexed to Tretter Decl. as Ex. 11.
49.	BMS knew that physicians working in office-based oncology practices considered spreads in making pharmaceutical product buying decisions.	Admitted that BMS knew from those physicians who inquired about spreads on BMS products that spreads might be one part of their consideration in pharmaceutical product buying decisions.
50.	BMS created spreads through special contract pricing and other discounting methods.	Admitted that BMS engaged in confidential contract pricing, rebates and other forms of discounting. Disputed that these practices were for the purpose of “creat[ing] spread” as opposed to responding to competitive marketplace forces. <u>See</u> Marre Dep. Tr. at 40-41, 79, annexed to Tretter Decl. as Ex. 11.
51.	BMS manipulated the spreads its drug Blenoxane in order to induce office-based oncology practices to purchase the drug.	Disputed. <u>See</u> response to Paragraph 46.

⁵ The “Bell BMS Decl.” refers to the expert declaration of Dr. Gregory K. Bell, Ph.D., dated March 15, 2006 in support of BMS's motion for summary judgment.

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52.	BMS manipulated the spreads its drug Cytosan in order to induce office-based oncology practices to purchase the drug.	Disputed. See response to Paragraph 46.
53.	BMS manipulated the spreads its drug VePesid in order to induce office-based oncology practices to purchase the drug.	Disputed. See response to Paragraph 46.
54.	BMS manipulated the spreads its drug Etopophos in order to induce office-based oncology practices to purchase the drug.	Disputed. See response to Paragraph 46.
55.	BMS manipulated the spreads its drug Rubex in order to induce office-based oncology practices to purchase the drug.	Disputed. See response to Paragraph 46.
56.	BMS manipulated the spreads its drug Taxol in order to induce office-based oncology practices to purchase the drug.	Disputed. See response to Paragraph 46.
57.	BMS manipulated the spreads its drug Paraplatin in order to induce office-based oncology practices to purchase the drug.	Disputed. See response to Paragraph 46.
58.	BMS actively marketed the spread between actual acquisition cost and AWP in order to take advantage of the importance that prescribers place on drug reimbursements.	Disputed. BMS did not “market spread;” rather, when asked be a prescriber it would provide truthful information about the AWP of a BMS drugs and its cost relative to a competing drug. Edwards Decl. ¶ 8, Ex. G (excerpts of deposition transcripts of BMS sales representatives).

In response to the last (un-numbered) paragraph of Plaintiffs' Statement, BMS states that the “documents and deposition testimony”, “references and source materials” and “record cites” that Plaintiffs purport to incorporate into their Statement speak for themselves and therefore do not call for an item by item response. BMS believes that the materials in fact contradict Plaintiffs' Statement and that the fragments cited by Plaintiffs are inapposite, inaccurate and taken out of context.

Dated: Boston, Massachusetts
April 7, 2006

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on April 7, 2006 a true and correct copy of the forgoing BMS DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Lyndon M. Tretter
Lyndon M. Tretter